DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
Atlanta, Georgia

SUMMARY MINUTES OF MEETING

Immunization Practices Advisory Committee

May 10-11, 1979

The Immunization Practices Advisory Committee met in Atlanta, Georgia, May 10-11, 1970. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT
- Dr. Thomas M. Vernon, Jr., Chairman
- Dr. Alan R. Hinman, Acting Executive Secretary
- Dr. E. Russell Alexander
- Dr. Suzanne E. Dandoy
- Dr. Maxine Hayes
- Dr. Edwin D. Kilbourne
- Dr. Jay P. Sanford
- Dr. Reuel A. Stallones
- Dr. Catherine M. Wilfert

Ex-officio
- Dr. William S. Jordan, NIAID

Liaison
- Dr. Edward A. Mortimer, Jr. (AAP)
- Dr. Theodore Doege, for Dr. Asher Finkel (AMA)
- Dr. J.M.S. Dixon (Canadian NACI)

COMMITTEE MEMBERS ABSENT

Ex-officio
- Dr. Harry Meyer, Jr., BoB

Liaison
- Dr. Asher Finkel, (AMA)

HEW STAFF PRESENT
- Dr. Louise Liang, OASH

CDC STAFF PRESENT

Office of Center Director
- Dr. William H. Foege, Director
- Mr. Donald Berreth, OI
- Mr. Charles Gozonsky, OGC

CDC STAFF (Continued)

Bureau of Epidemiology
- Dr. Claire Broome
- Dr. Terry England
- Dr. David Fraser
- Dr. Michael Gregg
- Dr. Eugene Hurwitz
- Dr. Melinda Moore
- Dr. Marjorie Pollack
- Dr. Lawrence Schonberger

Bureau of Laboratories
- Dr. Walter Dowdle
- Dr. Milford Hatch
- Dr. Gary Noble

Bureau of State Services
- Dr. David Brandling-Bennett
- Dr. John Frank
- Dr. Richard Goodman
- Dr. Isabel Guerrero
- Ms. Betty Hollingsworth
- Dr. Tim Nolan
- Dr. Stephen Preblud
- Ms. Kathy Rufo
- Dr. Mary Serdula

VISITORS
- Mr. Bill Daly, Lederle
- Mr. Bill McIntosh, Merck Sharp & Dohme
- Ms. Katherine B. McRae, Physicians Radio Network
- Mr. Marc A. Plattner, Connaught
- Mr. Douglas B. Reynolds, Connaught
- Mr. Kenneth B. Sandler, Connaught

Chairman Vernon called the meeting to order at 8:43 a.m., welcoming the members and Dr. Theodore Doege, who was representing Dr. Asher Finkel of the American Medical Association. Dr. Meyer and other representatives of the Bureau of Biologics (BoB) were unable to attend. Following general introductions members were polled as to any final comments they might have on the revised BCG recommendations. There were no last revisions suggested other than minor grammatical changes, and the revised statement will be published in the very near future.

Dr. Dowdle then described the Japanese approach to influenza vaccination. Children between the ages of 6 and 18 are required by law to receive 2 doses of vaccine each year. Approximately 80% of school children are estimated to receive at least 1 dose of influenza vaccine; more than 50% receive 2 doses every year. Very little attention is paid to "high-risk" groups or persons working in essential community services. Of 115 million people in Japan, approximately 11 million children received 2 doses of vaccine in 1977, and an additional 7 million received 1 dose. Only about 2 million adults received influenza vaccine that year.

It has been very difficult to establish whether or not this immunization program prevents influenza. There are school closures every year and, given that the program is a "universal" one, there has been no opportunity to monitor closures in schools where vaccination occurred versus where it did not. Excess mortality is calculated using an approach virtually identical to that used by CDC, and generally indicates mortality about twice that seen in the United States. There has not been any major decline in patterns of excess mortality since the program began. A full report on the Japanese National Influenza Vaccination Program will be submitted to the Committee within the next several weeks.

Discussion then turned to the Committee's views regarding the disposition of the swine influenza vaccine presently being stockpiled. There was general agreement that the likelihood of an epidemic of swine influenza was exceedingly small. Initial opinion ranged from discarding all of the vaccine to discarding only that which had been in wide circulation. There was concern about possible loss to potency of the vaccine, and Dr. Dixon reported that in Canada, ~~45~~ of 12 57 lots recently tested showed a significant loss of potency. This would indicate that for the Canadian vaccine (which was manufactured in Australia) the dosage would have to be increased if it was to be used. It was also noted that there would be some concern about using vaccine beyond its expiration date, and there might be a general unwillingness to use the older vaccine in any event. Nonetheless, the Committee generally was of the opinion that, should swine influenza recur and cause epidemics, it would be most useful to have this vaccine available for use until newer supplies can be manufactured, particularly since the vaccine can be stored at a cost of approximately 1/10 of 1 cent per dose per year. The Committee felt it quite unlikely that more than 40 million doses could be used in an "interim" period as described above and consequently recommended that Option 3 be adopted--that the 39.9 million doses on hand which had never left the manufacturers be retained if current testing demonstrates that it maintains potency. The Committee also felt it would be important to test the vaccine again in 1 year and recommended that the issue should be formally reevaluated at that time.

Dr. Dowdle then described the isolation of "Fukushima" influenza strains in Japan during the past influenza season. This strain is an H1N1 variant showing significant drift from the A/Brazil strain. Whether or not it will become the predominant strain in Japan or in the United States could not be predicted. It was also noted that an H1N1 variant of comparable degree of drift was noted in the United States at the beginning of the influenza season. While agreeing that these antigenic variants were worthy of note and study, the Committee supported the conclusion of its April 18 BoB workshop that no change in vaccine composition at this time was warranted.

Discussion then turned to the influenza vaccine recommendation for 1979-80. As part of this discussion, Dr. Schonberger reported on the experience with GBS during the past year. Eleven cases of GBS have been discovered in adults who had received vaccine within the preceding 8 weeks. This compared with 292 cases in adults who had not received influenza vaccine. The respective attack rates per million months of risk were 0.46 for vaccinees and 0.41 for those who did not receive vaccine. This yields a relative risk of 1.15, which is not statistically significant. By contrast, the relative risk during the swine influenza program was 6.23.

Few changes were made in the proposed statement which had previously been circulated to members. The statement will be published within the next 2-3 weeks in the Morbidity and Mortality Weekly Report (MMWR).

Following lunch, discussion turned to poliomyelitis. Dr. Melinda Moore summarized the 1979 polio experience in the United States. Eight cases were reported to the polio surveillance unit. Six of these were definitely vaccine-associated. Although a 7th was probably related to vaccine, it did not meet the strict criteria established for such classification. Specifically, this case occurred in an adult whose child had received polio vaccine 3 days and 70 days prior to onset of symptoms, whereas the epidemiological classification criteria call for the occurrence of polio 4-60 days following administration of vaccine to a household contact. In 1978 there was a predominance of cases in vaccine recipients rather than in contacts. Two recent cases of polio in the Amish community in Pennsylvania were described, and their possible relationship to the cases seen in members of the Dutch Reform Church in Canada and Holland last year was presented.

There was then discussion of newer data regarding inactivated polio vaccine and its effect on carriage of poliovirus. In the 1978 polio experience in Ontario, where IPV is used exclusively, 25% of family contacts of cases were culture-positive. However, of those who had received vaccine, only 11% were carrying the virus, whereas 37% of those who had not received vaccine had positive cultures. There was general agreement that the Committee continued to favor primary reliance on oral polio vaccine in the United States for the present time, and there was agreement that the Committee's statement should include specific recommendations for situations commonly encountered relating to travel, immunization of adults, and completion of interrupted schedules. Drs. Mortimer and Wilfert volunteered to attempt further revisions of the statement, and the meeting adjourned for the day at 5:05 p.m.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
Atlanta, Georgia

SUMMARY MINUTES OF MEETING

Immunization Practices Advisory Committee

May 10-11, 1979

The Immunization Practices Advisory Committee met in Atlanta, Georgia, May 10-11, 1970. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT
- Dr. Thomas M. Vernon, Jr., Chairman
- Dr. Alan R. Hinman, Acting Executive Secretary
- Dr. E. Russell Alexander
- Dr. Suzanne E. Dandoy
- Dr. Maxine Hayes
- Dr. Edwin D. Kilbourne
- Dr. Jay P. Sanford
- Dr. Reuel A. Stallones
- Dr. Catherine M. Wilfert

Ex-officio
- Dr. William S. Jordan, NIAID

Liaison
- Dr. Edward A. Mortimer, Jr. (AAP)
- Dr. Theodore Doege, for Dr. Asher Finkel (AMA)
- Dr. J.M.S. Dixon (Canadian NACI)

COMMITTEE MEMBERS ABSENT

Ex-officio
- Dr. Harry Meyer, Jr., BoB

Liaison
- Dr. Asher Finkel, (AMA)

HEW STAFF PRESENT
- Dr. Louise Liang, OASH

CDC STAFF PRESENT

Office of Center Director
- Dr. William H. Foege, Director
- Mr. Donald Berreth, OI
- Mr. Charles Gozonsky, OGC

CDC STAFF (Continued)

Bureau of Epidemiology
- Dr. Claire Broome
- Dr. Terry England
- Dr. David Fraser
- Dr. Michael Gregg
- Dr. Eugene Hurwitz
- Dr. Melinda Moore
- Dr. Marjorie Pollack
- Dr. Lawrence Schonberger

Bureau of Laboratories
- Dr. Walter Dowdle
- Dr. Milford Hatch
- Dr. Gary Noble

Bureau of State Services
- Dr. David Brandling-Bennett
- Dr. John Frank
- Dr. Richard Goodman
- Dr. Isabel Guerrero
- Ms. Betty Hollingsworth
- Dr. Tim Nolan
- Dr. Stephen Preblud
- Ms. Kathy Rufo
- Dr. Mary Serdula

VISITORS
- Mr. Bill Daly, Lederle
- Mr. Bill McIntosh, Merck Sharp & Dohme
- Ms. Katherine B. McRae, Physicians Radio Network
- Mr. Marc A. Plattner, Connaught
- Mr. Douglas B. Reynolis, Connaught
- Mr. Kenneth B. Sandler, Connaught

Chairman Vernon called the meeting to order at 8:43 a.m., welcoming the members and Dr. Theodore Doege, who was representing Dr. Asher Finkel of the American Medical Association. Dr. Meyer and other representatives of the Bureau of Biologics (BoB) were unable to attend. Following general introductions members were polled as to any final comments they might have on the revised BCG recommendations. There were no last revisions suggested other than minor grammatical changes, and the revised statement will be published in the very near future.

Dr. Dowdle then described the Japanese approach to influenza vaccination. Children between the ages of 6 and 18 are required by law to receive 2 doses of vaccine each year. Approximately 80% of school children are estimated to receive at least 1 dose of influenza vaccine; more than 50% receive 2 doses every year. Very little attention is paid to "high-risk" groups or persons working in essential community services. Of 115 million people in Japan, approximately 11 million children received 2 doses of vaccine in 1977, and an additional 7 million received 1 dose. Only about 2 million adults received influenza vaccine that year.

It has been very difficult to establish whether or not this immunization program prevents influenza. There are school closures every year and, given that the program is a "universal" one, there has been no opportunity to monitor closures in schools where vaccination occurred versus where it did not. Excess mortality is calculated using an approach virtually identical to that used by CDC, and generally indicates mortality about twice that seen in the United States. There has not been any major decline in patterns of excess mortality since the program began. A full report on the Japanese National Influenza Vaccination Program will be submitted to the Committee within the next several weeks.

Discussion then turned to the Committee's views regarding the disposition of the swine influenza vaccine presently being stockpiled. There was general agreement that the likelihood of an epidemic of swine influenza was exceedingly small. Initial opinion ranged from discarding all of the vaccine to discarding only that which had been in wide circulation. There was concern about possible loss to potency of the vaccine, and Dr. Dixon reported that in Canada, ~~45~~ 12 of 57 lots recently tested showed a significant loss of potency. This would indicate that for the Canadian vaccine (which was manufactured in Australia) the dosage would have to be increased if it was to be used. It was also noted that there would be some concern about using vaccine beyond its expiration date, and there might be a general unwillingness to use the older vaccine in any event. Nonetheless, the Committee generally was of the opinion that, should swine influenza recur and cause epidemics, it would be most useful to have this vaccine available for use until newer supplies can be manufactured, particularly since the vaccine can be stored at a cost of approximately 1/10 of 1 cent per dose per year. The Committee felt it quite unlikely that more than 40 million doses could be used in an "interim" period as described above and consequently recommended that Option 3 be adopted--that the 39.9 million doses on hand which had never left the manufacturers be retained if current testing demonstrates that it maintains potency. The Committee also felt it would be important to test the vaccine again in 1 year and recommended that the issue should be formally reevaluated at that time.

Dr. Dowdle then described the isolation of "Fukushima" influenza strains in Japan during the past influenza season. This strain is an H1N1 variant showing significant drift from the A/Brazil strain. Whether or not it will become the predominant strain in Japan or in the United States could not be predicted. It was also noted that an H1N1 variant of comparable degree of drift was noted in the United States at the beginning of the influenza season. While agreeing that these antigenic variants were worthy of note and study, the Committee supported the conclusion of its April 18 BoB workshop that no change in vaccine composition at this time was warranted.

Discussion then turned to the influenza vaccine recommendation for 1979-80. As part of this discussion, Dr. Schonberger reported on the experience with GBS during the past year. Eleven cases of GBS have been discovered in adults who had received vaccine within the preceding 8 weeks. This compared with 292 cases in adults who had not received influenza vaccine. The respective attack rates per million months of risk were 0.46 for vaccinees and 0.41 for those who did not receive vaccine. This yields a relative risk of 1.15, which is not statistically significant. By contrast, the relative risk during the swine influenza program was 6.23.

Few changes were made in the proposed statement which had previously been circulated to members. The statement will be published within the next 2-3 weeks in the Morbidity and Mortality Weekly Report (MMWR).

Following lunch, discussion turned to poliomyelitis. Dr. Melinda Moore summarized the 1979 polio experience in the United States. Eight cases were reported to the polio surveillance unit. Six of these were definitely vaccine-associated. Although a 7th was probably related to vaccine, it did not meet the strict criteria established for such classification. Specifically, this case occurred in an adult whose child had received polio vaccine 3 days and 70 days prior to onset of symptoms, whereas the epidemiological classification criteria call for the occurrence of polio 4-60 days following administration of vaccine to a household contact. In 1978 there was a predominance of cases in vaccine recipients rather than in contacts. Two recent cases of polio in the Amish community in Pennsylvania were described, and their possible relationship to the cases seen in members of the Dutch Reform Church in Canada and Holland last year was presented.

There was then discussion of newer data regarding inactivated polio vaccine and its effect on carriage of poliovirus. In the 1978 polio experience in Ontario, where IPV is used exclusively, 25% of family contacts of cases were culture-positive. However, of those who had received vaccine, only 11% were carrying the virus, whereas 37% of those who had not received vaccine had positive cultures. There was general agreement that the Committee continued to favor primary reliance on oral polio vaccine in the United States for the present time, and there was agreement that the Committee's statement should include specific recommendations for situations commonly encountered relating to travel, immunization of adults, and completion of interrupted schedules. Drs. Mortimer and Wilfert volunteered to attempt further revisions of the statement, and the meeting adjourned for the day at 5:05 p.m.

The Committee resumed its deliberations at 8:10 a.m. on the 11th of May. Dr. Mortimer proposed a revised organization of the statement to try to eliminate duplication and confusion. He and Dr. Wilfert then agreed to work as a subcommittee during the morning with staff to try to develop a final organization of the statement.

Dr. Hinman then described the mechanics of the adverse reaction monitoring system in place for use with Federally-provided vaccine. Vaccine recipients are asked to report to local or State health departments if any illness occurs that requires medical attention in the 4 weeks following vaccination. Tennessee was one of the first States to establish such a system on a pilot basis and has one of the most developed systems in the country at the present time. The recent association of DTP vaccination with sudden unexplained deaths in infants in Tennessee came to light because of the reaction surveillance system.

Dr. John Frank then described the situation in Tennessee and the investigation that was carried out there. An intensive effort was made to obtain information regarding the vaccination status and other characteristics of all infants between 6 weeks and 1 year of age who died suddenly in Tennessee in the period August 1978 - March 1979 and the same period one year previously. Overall, there was no increase in the occurrence of sudden death in infancy and there was no statistically significant increase in the proportion of infants dying suddenly who had received DTP vaccine at some time during their life or within the 1 week or 1 day prior to death. However, analysis of the time interval between DTP vaccination and sudden death demonstrated an unusual clustering in the 24 hours following vaccination. Members of the Committee concluded, as had participants in meetings in March at the Bureau of Biologics and April at the Center for Disease Control, that there was no convincing evidence of a causal relationship between DTP vaccination and sudden death in infancy, but that the temporal clustering was unexpected.

Given that sudden death in infancy has a peak incidence at 2-3 months, just the age when most infants receive DTP vaccine, the question was raised as to whether or not there was any indication for delaying the start of vaccination. Dr. Claire Broome presented data on deaths from pertussis in the United States from 1960 through 1974 which indicated that 30% of pertussis deaths had occurred in infants 3 to 5 months of age. In addition to the continuing risk, it was felt that infants are more likely to receive vaccine if given in the first months of life because of the greater likelihood that they will be brought in for general well-child care at that stage of their life. There was a unanimous view that delaying initiation of DTP vaccination was not warranted. It was also the view of the Committee that the proposal of Dr. Marcuse that DTP vaccination schedule be reduced to 2 doses in the first year of life was not adequately documented by available evidence. There was great enthusiasm for the prospect of administering oral polio vaccine along with DTP and measles-mumps-rubella vaccines in the second year of life, although direct data to support this simultaneous administration were not presently available.

Drs. Mortimer and Wilfert then reported back on the proposed organization of the polio statement and, following initial discussion, it was clear that the members felt it necessary to be able to review the formal proposal at some leisure. In consequence, it was agreed that the proposed revision would be mailed out to the members and that an attempt would be made to come to agreement on the statement by mail before the next meeting.

Because of recent discussion about the possible association between mumps vaccine and diabetes, Dr. Stephen Preblud then summarized available information for the Committee's interest. It was clear to Committee members that there was no present basis for considering that mumps vaccine was in any way related to the development of juvenile diabetes.

Calendars for marking potential dates for a fall meeting in the latter part of September or during October or early November were distributed to members, and the meeting adjourned at 12:45 p.m.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

Thomas M. Vernon M.D. 5-23-79

Thomas M. Vernon, Jr., Chairman Date